

106TH CONGRESS  
2D SESSION

# S. 2625

To amend the Public Health Service Act to revise the performance standards and certification process for organ procurement organizations.

---

## IN THE SENATE OF THE UNITED STATES

MAY 24, 2000

Ms. COLLINS (for herself, Mr. DODD, Mr. HUTCHINSON, Mr. WELLSTONE, Mr. TORRICELLI, Mr. MURKOWSKI, Mr. DORGAN, Mr. LIEBERMAN, and Mr. MOYNIHAN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

## A BILL

To amend the Public Health Service Act to revise the performance standards and certification process for organ procurement organizations.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. ORGAN PROCUREMENT ORGANIZATION CER-**  
4 **TIFICATION ACT OF 2000.**

5 (a) FINDINGS.—Congress makes the following find-  
6 ings:

7 (1) Organ procurement organizations play an  
8 important role in the effort to increase organ dona-  
9 tion in the United States.

1           (2) The current process for the certification and  
2           recertification of organ procurement organizations  
3           conducted by the Department of Health and Human  
4           Services has created a level of uncertainty that is  
5           interfering with the effectiveness of organ procure-  
6           ment organizations in raising the level of organ do-  
7           nation.

8           (3) The General Accounting Office, the Insti-  
9           tute of Medicine, and the Harvard School of Public  
10          Health have identified substantial limitations in the  
11          organ procurement organization certification and re-  
12          certification process and have recommended changes  
13          in that process.

14          (4) The limitations in the recertification process  
15          include:

16                (A) An exclusive reliance on population-  
17                based measures of performance that do not ac-  
18                count for the potential in the population for  
19                organ donation and do not permit consideration  
20                of other outcome and process standards that  
21                would more accurately reflect the relative capa-  
22                bility and performance of each organ procure-  
23                ment organization.

24                (B) A lack of due process to appeal to the  
25                Secretary of Health and Human Services for

1           recertification on either substantive or proce-  
2           dural grounds.

3           (5) The Secretary of Health and Human Serv-  
4           ices has the authority under section 1138(b)(1)(A)(i)  
5           of the Social Security Act (42 U.S.C. 1320b-  
6           8(b)(1)(A)(i)) to extend the period for recertification  
7           of an organ procurement organization from 2 to 4  
8           years on the basis of its past practices in order to  
9           avoid the inappropriate disruption of the nation's  
10          organ system.

11          (6) The Secretary of Health and Human Serv-  
12          ices can use the extended period described in para-  
13          graph (5) for recertification of all organ procure-  
14          ment organizations to—

15                (A) develop improved performance meas-  
16                ures that would reflect organ donor potential  
17                and interim outcomes, and to test these meas-  
18                ures to ensure that they accurately measure  
19                performance differences among the organ pro-  
20                curement organizations; and

21                (B) improve the overall certification proc-  
22                ess by incorporating process as well as outcome  
23                performance measures, and developing equitable  
24                processes for appeals.

1 (b) CERTIFICATION AND RECERTIFICATION OF  
2 ORGAN PROCUREMENT ORGANIZATIONS.—Section  
3 371(b)(1) of the Public Health Service Act (42 U.S.C.  
4 273(b)(1)) is amended—

5 (1) by redesignating subparagraphs (D)  
6 through (G) as subparagraphs (E) through (H), re-  
7 spectively;

8 (2) by realigning the margin of subparagraph  
9 (F) (as so redesignated) so as to align with subpara-  
10 graph (E) (as so redesignated); and

11 (3) by inserting after subparagraph (C) the fol-  
12 lowing:

13 “(D) notwithstanding any other provision of  
14 law, has met the other requirements of this section  
15 and has been certified or recertified by the Secretary  
16 within the previous 4-year period as meeting the  
17 performance standards to be a qualified organ pro-  
18 curement organization through a process that  
19 either—

20 “(i) granted certification or recertification  
21 within such 4-year period with such certification  
22 or recertification in effect as of January 1,  
23 2000, and remaining in effect through the ear-  
24 lier of—

25 “(I) January 1, 2002; or

1 “(II) the completion of recertification  
2 under the requirements of clause (ii); or

3 “(ii) is defined through regulations that  
4 are promulgated by the Secretary by not later  
5 than January 1, 2002, that—

6 “(I) require recertifications of quali-  
7 fied organ procurement organizations not  
8 more frequently than once every 4 years;

9 “(II) rely on outcome and process per-  
10 formance measures that are based on em-  
11 pirical evidence, obtained through reason-  
12 able efforts, of organ donor potential and  
13 other related factors in each service area of  
14 qualified organ procurement organizations;

15 “(III) use multiple outcome measures  
16 as part of the certification process; and

17 “(IV) provide for a qualified organ  
18 procurement organization to appeal a de-  
19 certification to the Secretary on sub-  
20 stantive and procedural grounds;”.

○